K000119

FEB 17 2000

510(k) Summary
(as Required by 21 CFR § 807.92)

A. Submitters Information

Submitter's Name:	St. Jude Medical Heart Valve Division
Address:	St. Jude Medical, Inc. One Lillehei Plaza St. Paul, MN 55117
Telephone Number:	(612) 483-2000
Submission Prepared:	January 12, 2000

B. Device Information

Proprietary Name:	SJM Tailor™ annuloplasty ring
Common or Usual Name:	Flexible Annuloplasty Ring "C" ring
Classification Name:	Pre-amendment Class III CFR § 870.3800 Cardiovascular Prosthetic Devices, Annuloplasty Ring
Predicate Device:	St. Jude Medical considers The SJM Tailor™ annuloplasty ring (without Silzone) to be substantially equivalent to the SJM Tailor™ annuloplasty ring with Silzone® coating.
Device Description	
Intended Use:	The SJM Tailor™ Annuloplasty Ring is indicated for use in repair of diseased or damaged mitral or tricuspid heart valves that are determined by the physician to be repairable and do not require replacement.

C. Comparison of Required Technological Characteristics

SJM considers the Tailor ring (without Silzone) is substantially equivalent in configuration, function and intended use to the Tailor ring with Silzone. The table below is a comparison of the equivalency characteristics between the two devices.

	Characteristic	Equivalency
a.	Product Labeling	Substantially Equivalent
b.	Intended Use	Identical
c.	Physical Characteristics	Substantially Equivalent
d.	Anatomical Sites	Identical
e.	Target Population	Identical
f.	Performance Testing	Substantially Equivalent
g.	Safety Characteristics	Substantially Equivalent

D. Summary of Non-Clinical Tests

The testing for the SJM Tailor™ annuloplasty ring with Silzone® coating model TAR (predicate) can be found in the premarket notification (K981656). The following tests have been performed on the SJM Tailor™ annuloplasty ring model TARN to insure substantial equivalence with the predicate.

1. New Suture Evaluation
   - Tensile Strength
   - LAL
   - Visual Inspection
   - Biocompatibility

2. Physical Testing
   - Ring Assembly
   - Steam Sterilization
   - Ring Diameter
   - Cut Ring Evaluation
   - Fabric Seam Evaluation (Suture Pullout)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2000

Mr. William McKelvey
Regulatory Affairs Coordinator
St. Jude Medical, Inc.
One Lillehei Plaza
St. Paul, MN 55117

Re: K000119

Trade Name:	Tailor Annuloplasty Ring Model TARN
Regulatory Class:	III
Product Code:	KRH
Dated:	January 12, 2000
Received:	January 18, 2000

Dear Mr. McKelvey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular, Neurological
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000119

Device Name: **SJM® Tailor™ annuloplasty ring**

Indications for Use:

The SJM® Tailor™ annuloplasty ring is indicated for use in the repair of a mitral or tricuspid valve that is diseased or damaged due to acquired or congenital processes.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000119

Prescription Use X or Over-The-Counter Use ____

Per 21 CFR 801.109) Optional Format 1-2-96)